



HIV Medicine Association
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2004D-0193

RE: Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products

Submitted by the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA). Please contact Christine Lubinski, HIVMA Executive Director for questions, comments, or follow-up. Phone: 703-299-1215
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We are writing on behalf of the HIV Medicine Association (HIVMA) Board of Directors and our more than 2,700 physician, scientist, and other health care professional members who devote their careers to HIV/AIDS. Thank you for the opportunity to comment on the *Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)*. We appreciate the importance of this document that was developed to assist industry with screening cell and tissue donors to reduce the risk of transmitting communicable diseases such as HIV disease.

We comment on the guidance because of our commitment to promoting federal policies that are grounded in science. We also comment on this particular guidance to strongly encourage the Food and Drug Administration (FDA) to reevaluate its donor screening recommendations for HIV disease that do not reflect the current standard of HIV testing or current trends in the modes of transmission of HIV infection.

The FDA approved the Nucleic Acid Amplification Test (NAT) to screen whole blood donors for HIV infection and hepatitis C virus (HCV) in 2002. However, the two citations referenced in the guidance that informed the HIV screening recommendations are guidelines published by the Centers for Disease Control and Prevention (CDC) in 1994 and transcripts from a FDA Blood Advisory Committee meeting held in 2001. Our recommendations for revising the guidance for the sections relevant to screening for HIV disease in part reflect the fact that with the use of the NAT test, the window period for detecting HIV infection has been reduced to 12 days.¹

Our comments also recognize that HIV disease is transmitted via behaviors and that it is outdated and discriminatory to exclude all men who have had sex with men, which is essentially

¹ FDA Talk Paper: *FDA Approves First Nucleic Acid Test (NAT) System to Screen Whole Blood Donors for Infections with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)*. February 28, 2002. Available online at: <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01140.html>.

what the FDA proposal that male donors who have had sex with another man in the previous five years does. Doing so ignores the fact that HIV is transmitted via unprotected heterosexual and homosexual sex, and that the CDC estimates that 33 percent of new HIV infections result from heterosexual sex.²

SPECIFIC COMMENTS ON GUIDANCE DOCUMENT

What risk factors do I look for when screening a donor? (page 16 of the guidance)

This section outlines questions to screen and disqualify potential donors for an array of communicable diseases including HIV infection. In regard to questions related to HIV infection, we recommend replacing screening questions 1, 2, 4, 5 with the following:

1. persons who have had unprotected sex with a person of unknown HIV status within the past six months
2. persons who have injected drugs for non-medical reasons within the past six months, including intravenous, intramuscular, or subcutaneous injections

At a minimum, the proposed exclusion for persons who have had sex with an at-risk group in the previous 12 months and persons who may have been exposed to contaminated blood products in the previous 12 months should be applied to all individuals who may be at risk for HIV infection, including men who have had sex with men, injection drug users and commercial sex workers. The five-year exclusion period is arbitrary and unnecessary given the advances in HIV testing technology.

There will always be a very slight risk for HIV infection through donated cell and tissue products regardless of the screening policies, and we believe that persons receiving these products should be informed of that risk. Nevertheless, we hope that FDA will give serious consideration to developing consistent HIV donor screening recommendations that respond to the current knowledge about HIV transmission and current HIV testing capabilities. The current recommendations needlessly limit and strain the donor pool while sending a message that sexual orientation itself is a primary risk factor for the transmission of a deadly infectious disease. Furthermore, failure to screen all donors based on behaviors potentially places recipients at greater risk for HIV infection because of the fact that 33 percent of new cases are transmitted via heterosexual sex.

Finally, we would urge you to review FDA screening policies for blood and organ donation, which contain different, and from our point of view, inappropriate exclusionary criteria for donations from men who have sex with men. We see no scientific justification to recommend different windows of time for donor exclusion, and would encourage the FDA to adopt a consistent, science-based approach to donor screening as we propose, for the donation of all of these body products.

² CDC. HIV/AIDS UPDATE: A Glance at the HIV Epidemic. Available online at <http://www.cdc.gov/hiv/stats/hasrsupp.htm>.